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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ERIN ALLEN, et al, on behalf of herself and all
others similarly situated,

Plaintiff,

v.

CONAGRA FOODS INC. a Delaware
corporation,

Defendant.

No. 3:13-cv-01279 (WHO)

**PLAINTIFF'S MOTION FOR
PARTIAL SUMMARY
JUDGMENT (REDACTED
VERSION OF DOCUMENT
FILED UNDER SEAL)**

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HONORABLE JUDGE ORRICK

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I. INTRODUCTION

Conagra prominently labels Parkay Spray as fat- and calorie-free despite the fact it is 44% fat by weight and contains [REDACTED]. Conagra rationalizes its lie by defining the serving size for Parkay Spray as “one spray” (.2g) for cooking and “five sprays” (1g) for topping—amounts so ridiculously small that Conagra could round down the disclosed amount of fat to zero. Unsurprisingly, this serving-size manipulation is unlawful. FDA regulations establish standardized serving sizes for 131 food product categories in the form of a Reference Amount Customarily Consumed (“RACC”) based on national survey data regarding consumption patterns. Food manufacturers are *required* to use the RACC serving size for food products that fit in the specified category based on the “*major intended use*” of the product. Conagra cannot use the “one spray for cooking” serving size because the evidence is undisputed that the product’s “major intended use” is as a topping, not a cooking spray. Manufacturers may include a second column of nutritional information for a secondary use type, but *only* if they have evidence of a different amount “*customarily consumed.*” Conagra cannot justify the secondary “five spray for topping” serving size because no evidence supports that usage amount. As Parkay Spray is a buttery flavored liquid margarine, Conagra was required to use the RACC for butter, margarine, and their substitutes of one tablespoon or 14 grams, meaning it was required to disclose approximately [REDACTED]

Judge Tigar stated that “the question posed by this consumer fraud action” is whether “Parkay Spray [is] more like Pam® or liquid butter.” Dkt. 41 at 1. This Court later refined that characterization to focus on Parkay Spray’s “major intended use,” stating that the issue is not merely whether “some consumers choose to use Parkay Spray as a topping but rather [whether] ConAgra markets it to be used in that way by communicating to consumers that it is a butter substitute.” Dkt. 213, 16-17, citing 21 C.F.R. § 101.12.

The evidence is in, and the undisputed facts show a clear answer: Parkay Spray’s major intended use is as a liquid butter-flavored topping, not a cooking spray. Conagra’s 30(b)(6) witness testified that [REDACTED]

1 [REDACTED] All of Conagra's internal marketing
2 documents [REDACTED]

3 [REDACTED]. Not one internal document from Conagra [REDACTED]

4 [REDACTED] Conagra even [REDACTED]

5 Parkay Spray's physical properties demonstrate it is simply a manually sprayable liquid butter
6 substitute, not suitable for use as a cooking spray.

7 The only evidence Conagra has to support its cooking spray theory was manufactured by its
8 attorneys after this lawsuit commenced, and none of it is sufficient to create a genuine fact issue.
9 The Butler survey it offers to show that consumers use Parkay Spray primarily as a cooking spray
10 is so methodologically flawed that it is not admissible under *Daubert*; Butler not only primed
11 respondents by misrepresenting the product name as "Parkay cooking spray/topping," but asked
12 them to recall usage from the prior *eight years* despite the FDA RACC survey methodology
13 requiring contemporaneous diaries or usage in the prior *twenty-four hours*. The FDA
14 correspondence Conagra offers is similarly worthless. It fails to comply with FDA procedures for
15 official agency advisory opinions, meaning it is not a statement of agency interpretation or binding
16 in any fashion, and is, in fact, not evidence at all. The correspondence is also based on an
17 incomplete analysis of the underlying regulations and factual assumptions that are facially false.
18 The Court can simply disregard it.

19 Because the undisputed facts show that Parkay Spray's major intended use is as a liquid
20 butter substitute, not a cooking spray, Plaintiff is entitled to partial summary judgment that
21 Conagra's label violated FDA regulations and was, therefore, unlawful under the UCL.

22 II. STATEMENT OF FACTS

23 A. **Parkay Spray is a Butter Substitute Made of 44% Fat that Conagra 24 Nonetheless Advertises Has Zero Fat and Zero Calories.**

25 Conagra manufactures, distributes, markets, advertises, and sells, in the state of California,
26 a buttery topping product named Parkay Buttery Spray ("Parkay Spray"). Parkay Spray's front
27 label indicates that it is "44% vegetable oil" (a fat), which makes it a vegetable oil "spread" under
28

industry nomenclature. Exs. 1-3; Ex. 4 at 2.1 [REDACTED]
 [REDACTED]. Ex. 5. The label lists water, soybean oil,
 and buttermilk as the main ingredients by weight. Exs. 1-3. These ingredients are virtually identical
 to those for other Parkay tablespreads, such as Parkay Sticks, Tubs, and Squeeze (a squeezable
 version of Parkay margarine), except that Parkay Spray has more water. *Id.*; Patek Decl., ¶ 8
 (Parkay Spray is [REDACTED] water); Ex. 6; Ex. 7. Parkay Spray and some Parkay spreads also differ from
 margarine due to the addition of “sweet cream buttermilk” to make them taste more like butter.
 Exs. 8-9. Essentially, Parkay Spray is butter-flavored margarine diluted with enough water to
 dispense it via a pump-action bottle. Ex. 6; Ex. 10 at 5; Ex. 11 at 71:1-74:7 (testifying that [REDACTED]
 [REDACTED]).

Despite Parkay Spray’s high fat content, Conagra markets it as fat- and calorie-free. In
 2007, Conagra added to Parkay Spray’s front label the words “Fat Free” and “Zero Calories” in a
 prominent logo at the top of the bottle, centered around a large “0.” Compare Ex. 1 (2007 Label)
 with Exs. 17-18 (prior labels). In 2009, after recognizing that the product “does not meet the
 definition of ‘Fat Free’ per the regulations,” Conagra changed “Fat Free” to “0g Fat” and added
 “Per Serving” to the logo. Ex. 2. The “Nutritional Info” on the back label, which has not changed
 since at least 2008, similarly represents that Parkay Spray has “0g” of fat per serving and “0
 Calories” per serving. Ex. 3. In contrast, other Parkay tablespreads list “7 g” to “9 g” of fat content
 per serving, with “light” tablespreads (which are 39% vegetable oil) going as low as “5 g.” Ex. 6.

Conagra makes its 0g fact and 0 calories representations based on Parkay Spray’s purported
 serving sizes, which Conagra lists as “1 spray (0.2 g) for cooking” or “5 sprays (1 g) for topping.”
 Exs. 1-3. As discussed further below, Conagra [REDACTED]
 [REDACTED]. The serving size Conagra uses for all other table spreads—one
 tablespoon—is 14 grams. Ex. 6; Ex. __ [Fitz Tr.] at 250:12-251:2 (Fitzgerald, testifying [REDACTED]
 [REDACTED]). Had Conagra used the serving size
 required for butter-substitutes, the label would have disclosed [REDACTED] of fat per serving. Ex. 5; Ex. 13.

¹ Unless otherwise indicated, all exhibits (“Ex.”) cited are attached to the Declaration of Anthony Patek in Support of Plaintiff’s Motion for Summary Judgment, filed herewith.

B. FDA Regulations Require a One Tablespoon Serving Size for Vegetable Oil Spreads.

FDA serving size regulations (discussed in further detail in section III.A, below) require companies to choose a “reference category” that has a standard serving size called an RACC. 21 C.F.R. § 101.12(a)(7). Each reference category is based on the “major intended use” of the product. 21 C.F.R. § 101.12(a)(7). Substitute or altered foods, such as a “low calorie” version, must use the same RACC as the food for which it is offered as a substitute. 21 C.F.R. 101.12(d). Under FDA guidance, “[a]ll types of *butter and margarine* (regular, diet, *liquid*, and whipped), *spreads*; oils, and shortenings” are within the “butter, margarine, oil, shortening” reference category. Dkt. 90-21 (“FDA Guide”) (emphasis added). The reference amount for the “butter, margarine, oil, shortening” category is one tablespoon.

C. Parkay Spray is a Vegetable Oil Spread.

1. Conagra’s 30(b)(6) Witnesses Testified that Parkay Spray is a Vegetable Oil Spread Used Almost Exclusively as a Topping.

Patrick Fitzgerald, Conagra’s 30(b)(6) designee on the topic of consumer usage and Senior Manager for Conagra’s Tablespread Portfolio—which includes Parkay Spray—testified that

Ex. 12, at 171:7-174:25; *see also id.* at 147:15-19

). Fitzgerald further acknowledged that,

Id. at 174:23-25 (Q.

Fitzgerald further admitted that

” *Id.* at 162:4-7. Catharine

Bartholomew, Senior Director of Conagra’s Consumer Insights Group, and 30(b)(6) designee on the topic of survey data, corroborated Mr. Fitzgerald, testifying that products within the Parkay brand are “ ” Ex. 14 at 199:7-12.

2. Conagra Markets Parkay Spray as a Butter-Flavored Topping.

Mr. Fitzgerald further admitted that

Ex. 12 at 198:14-17, and that

Id. at 47:19-48:3.

Mr. Fitzgerald further testified that Conagra places Parkay Spray displays in places

.” *Id.* at 94:23-95:16.

He admitted that Conagra intends that Parkay Spray be

.” *Id.*; see also *id.* at 62:14-63:9

See also Ex. 15 at 31:6-32:19.

Mr. Fitzgerald justified Conagra’s focus on consumers’ use of Parkay Spray as a topping by

Ex. 12 at 202:7-14; *see also* Ex. 16 at col. 5

Conagra’s advertising focuses on Parkay Spray’s ability to flavor foods, not cook them. Since 2007, Parkay Spray’s label has included the tagline “fresh and creamy taste.” Exs. 1-3. It pictures corn on the cob with a “coating” of a buttery topping. *Id.*; Ex. 12 at 127:10-128:6. Conagra uses similar pictures of corn with a buttery topping in its Parkay Spray in-store displays, circulars, and web advertisements. Exs. 19-22. Conagra’s website advertises Parkay Spray with: “Get the buttery taste of Parkay on all your favorite foods with zero calories per serving! It’s the guilt-free way to top vegetables, potatoes, poultry, and so much more.” *See* Ex. 23.

Conagra treats Parkay Spray as a spread throughout the marketing process. Conagra’s tablesreads team

CAGAL_009067

[REDACTED] and CAGAL_009071 [REDACTED]
 [REDACTED]; Ex. 12 at 194:24-195:4 and 236:5-8
 (Tablespread Portfolio manager, testifying [REDACTED];
 Ex. 25 (Conagra Tablespreads Overview, [REDACTED]
 [REDACTED]) at 9-16; Ex. 26, at CAGAL_001853 (Tablespreads Portfolio
 Analysis: [REDACTED]. That portfolio is [REDACTED]
 [REDACTED] Ex. 30 at 12:21-14:3 (VP Sears, testifying [REDACTED]
 [REDACTED] When performing competitive analyses and tracking
 sales, the “tablespreads” team [REDACTED]. Exs. 4 at
 CAGAL_009077-79 ([REDACTED]), Ex. 10 at CAGAL_008674
 (“Tablespreads Overview,” [REDACTED]
 [REDACTED]) and at CAGAL_008681 ([REDACTED] Ex.
 25 at CAGAL_007833 [REDACTED]); Ex.
 28 at CAGAL_010962 (Parkay Planning document [REDACTED]
 [REDACTED]; Ex. 29, at CAGAL_001911 (Conagra Pricing Tracker [REDACTED]
 [REDACTED]); Ex. 30 at CAGAL_001853 (Tablespread Portfolio
 Analysis, showing [REDACTED] cf. Ex. 12 at 199:5-200:20
 [REDACTED] Conagra’s tablespreads team also
 uses a variety of terms to describe Parkay Spray not only as a spread, but as a butter/margarine
 substitute, such as [REDACTED],” all of which are
 consistent with the food industry’s terminology for Parkay Spray and similar sprayable vegetable
 oil spreads. *Compare, e.g.*, Ex. 26 (titled “Butter Spray” Strategic Plan); Ex. 10 at
 CAGAL_008674 [REDACTED] Ex. 25 at CAGAL_007859 [REDACTED]
 [REDACTED]); with Ex. 31 at CAGAL_970 (IRI price tracking study, classifying Parkay Spray as
 “[REDACTED]”); Ex. 20 at CAGAL_2316-17 and CAGAL_002322-23 ([REDACTED]
 [REDACTED] Ex. 32 at
 CAGAL_970 (IRI Tablespreads Scorecard, [REDACTED]); Ex. 16 at 5 (NPD
 market survey, referring to “[REDACTED]”); Ex. 34 at CAGAL_000213 (Mintel

report, [REDACTED]).

Conagra even [REDACTED]

Exs. 41-42. By contrast, a one second spray of Pam covers a 10-inch pan, even when held much farther away. Ex. 43; *compare* Ex. 50 at 40:18-21 (Pam spray test conducted at distance of 10"-12") with *id.* at 26:24-27:20 & 29:23-30:7 ([REDACTED]).

3. All Independent Market Reports Relied Upon by Conagra Identify Parkay Spray as a Spread or Topping

Conagra maintains [REDACTED]

[REDACTED] Ex. 14 at 40:10-42:25; 152:19-153:14 and 194:23-198:21. [REDACTED]

Id.

The National Eating Trends ("NET") survey—a diary-based survey that collects data on how consumers use products as they are using them—states [REDACTED] Ex. 16; Ex.

14 at 153:19-156:18 (Bartholomew, [REDACTED])

see also Ex. 12 at 171:7-172:12 (Fitzgerald, [REDACTED])

[REDACTED]). In contrast, NET reports [REDACTED]

Ex. 16 at 1. Conagra [REDACTED]

Ex. 44; Ex. 33, 1. NET is [REDACTED]

[REDACTED] Ex. 14 at 153:19-154:4; *see also id.* at

176:6-16 ([REDACTED])

[REDACTED]), 177:16-178:23 ([REDACTED]); Ex. 12 at 160:1-15 and

161:15-162:17 ([REDACTED]). Fitzgerald

testified [REDACTED] *Id.* at 174:23-175-7.

IRI, a leading retail purchase tracker, [REDACTED] Ex. 31

at CAGAL_000959 ([REDACTED])

Ex. 46 at CAGAL_008374 ([REDACTED]). It

also [REDACTED] Id. at CAGAL_008387 ([REDACTED]). IRI [REDACTED]. Ex. 12 at 200:21-201:1 (Fitzgerald: “[REDACTED] According to Conagra’s Senior Director of Consumer Insights, Catharine Bartholomew, [REDACTED] Ex. 14 at 187:1-8; 194:23-195:19 (demographics); 268:2-274:9 (price promotion); Ex. 12 at 200:1-20 (Fitzgerald, testifying that [REDACTED]).

Mintel publishes a periodic market report on “Butter, Margarine, and Spreads,” which includes survey-based demographic and use data. Exs. 34 and 45. Ms. Bartholomew testified that [REDACTED] Ex. 14 at 163:15-164:10, 228:3-230:14. Mintel’s 2008 report [REDACTED] Ex. 34 at CAGAL_000211 [REDACTED]), CAGAL_000213 [REDACTED] CAGAL_000216 [REDACTED] . Mintel’s 2011 report [REDACTED] Ex. 45 at CAGAL_009250 and -9263.

Similarly, when [REDACTED] Ex. 47 at 12. Global Research Partners further [REDACTED] Id. at 18.

D. Parkay Spray is Not an Effective Cooking Spray, and is Not Marketed as One

As noted previously, Conagra rationalizes its 0.2 g single spray serving size by classifying Parkay Spray’s “main intended use” as “cooking spray.” It is not.

1. “Cooking Sprays” are Non-Stick Cooking Aids

A cooking spray prevents food from sticking to a cooking surface. *See* Ex. 11 at 31:1-13 (cooking sprays contain non-stick agent); Ex. 48 at ¶ 2 (Conagra patent application, identifying “cooking sprays” as non-stick “cookware release” compositions); <https://www.merriam-webster.com/dictionary/cooking%20spray> (accessed June 12, 2020) (“cooking spray” is “an aerosol that contains vegetable oil for spraying on cookware *to prevent food from sticking*”) (emphasis added); https://en.wikipedia.org/wiki/Cooking_spray (accessed June 12, 2020) (“Cooking spray is a spray form of an oil as a lubricant, lecithin as an emulsifier, and a propellant such as food-grade alcohol, nitrous oxide, carbon dioxide or propane. Cooking spray is applied to frying pans and other cookware to prevent food from sticking.”); *see also* Ex. 30 at 26:20-27:23, 41:6-15 (______). They usually contain oil, a non-stick or release agent, and a propellant. Ex. 48 at ¶ 2. The release agent can be up to 20% of the cooking spray’s ingredients by weight, though a preferred composition is about 6% lecithin. *Id.* at ¶ 54. A defining characteristic of cooking sprays is their ability to prevent food residue “build-up” on pans, _____. Ex. 48 at ¶ 2; Ex. 49 at CAG_017000. Pam and other non-stick cooking sprays are shelf-stable for up to two years and are sold in the non-refrigerated baking aisle. Ex. 11 at 16:2-17; 19:9-20:2. Historically, they contained little or no water. Ex. 43 (water listed as non-primary ingredient); Ex. 11 at 63:16-65:20 (______). Cooking sprays are typically pressurized so that pump-action is not required to dispense them. Ex. 48 at ¶ 2.

2. Conagra Testimony and Documents Show Parkay Spray is Not Marketed or Designed as a Cooking Spray.

Conagra employees admitted that Parkay Spray does not compete in the cooking spray category; Pam is its product in that category. Ex. 30 at 13:6-14:1 (______); Ex. 12 at 174:23-175:5 (______). They also testified that Conagra does not _____ Ex. 14 at 232:8-233:14 (“_____.”); Ex. 12 at 235:12-23 (“_____”).

Ex. 12 at 137:25-140:8 & 204:23-205:5

). Conagra even admits that

Id.

In contrast to the numerous documents treating Parkay Spray as a “spread,” Conagra has not produced a single internal marketing document that *mentions* use of Parkay Spray as a cooking spray, much less any that focus on this as the product’s primary intended use. Patek Decl., ¶ 75.

Conagra’s records corroborate this testimony. *Id.* Despite having a dedicated cooking spray team,

no

advertisements touting this use, and no cooking-spray-oriented promotions. *Id.* Nor are there

. *Id.*; Ex. 50 at 42:5-43:8 (Parkay Spray

engineer Ewart, Conagra has

Ex. 36

Conagra sells Parkay Spray in the dairy section alongside butters and margarines, while Pam and other non-stick sprays are sold in the non-refrigerated baking aisle. *Id.*

Conagra’s web site underscores that Conagra does not intend Parkay Spray for cooking—whether as a nonstick agent or in any other way. While Conagra’s web site posts at least 99 recipes using other Parkay spreads as a butter-flavored ingredient, and 971 recipes citing use of Pam as a cooking spray, it includes no recipes using Parkay Spray. Patek Decl., ¶ 25, Ex. 35.

Conagra also informs consumers who reach out to it that they “*Id.*, Ex. 36 [CAGAL_006091] (caseid 60580690; *see also* caseid 52719547,

Exs. 37-40.

Conagra’s design choices show that Parkay Spray is not intended for use as a cooking

spray. Unlike Pam, Parkay Spray contains over 50% water. Patek Decl., Ex. 7 ([REDACTED]); Ex. 11 at 63:4-64:18 ([REDACTED]); Ex. 51 at ¶¶ 14 & 27-31. At the temperatures required to properly sauté food, the water in Parkay Spray will have boiled off. *Id.*; Ex. 11 at 59:8-61:25. A 0.2 gram spray of Parkay Spray yields only 0.09 grams of oil, so it takes three sprays of Parkay Spray to deliver > 0.25 grams of oil. *Id.* In contrast to pressurized cooking sprays, Parkay Spray’s nozzle must [REDACTED] . Ex. 51, ¶ 47; Ex. 42. Further, as discussed above, Parkay Spray’s small diameter spray pattern is insufficient to cover a pan. *Id.*; Ex. 51, ¶¶ 49-50; Ex. 43. And because Parkay Spray contains milk fat, it creates a dark, sticky residue when used at cooking temperatures. Ex. 51, ¶¶ 34-44; *see also* Ex. 11 at 35:13-36:25 ([REDACTED]); Ex. 36 (Conagra complaint, [REDACTED]). Further, Parkay Spray must be refrigerated and has a shelf-life of about 6 months, while Pam and other non-stick sprays are shelf-stable for up to two years. *Id.* When asked how Conagra chose the cooking spray RACC, Conagra’s Senior Director of Nutrition and Food Labelling, Mr. Chatzidakis, said it [REDACTED] . *Id.* at 159:2-18.

E. Conagra’s “5 Spray” Secondary Serving Size for Parkay Spray as a “Topping” is Arbitrary and Based on No Real Evidence

1. Parkay Spray’s “5 Spray” Serving Size “For Topping” is Based on Conagra’s “Marketing Intuition,” Not Data.

Conagra provides a secondary “5 Sprays” (1 gram) serving size for Parkay Spray when used as a “topping.” When asked to identify Conagra’s basis for “5 Sprays”, Mr. Chatzidakis, [REDACTED] ” Ex. 52 at 179:10-181:7. The 30(b)(6) designees for consumer usage and market research [REDACTED] y.2 Ex. 12 at 248:21-250:2; Ex. 14 at

² Conagra has stipulated that “the fat, calories and serving size information in the [Parkay Spray] nutrition facts panel stayed the same from 1998, approximately, when the brand was acquired, until 2009 without [Conagra] having any evidence that anybody reviewed or reconsidered those points during that time period.” Ex. 52 at 175:3-20.

247:21-248:25 (“[REDACTED]”). Asked why, in the absence of consumer data, Conagra settled on five sprays as opposed to, e.g., four or seven, Fitzgerald responded “[REDACTED]” Ex. 12 at 254:22-255:11. He also testified that the five-spray serving size was based on [REDACTED].” *Id.* (emphasis added). Conagra’s “marketing intuition” conveniently picked a serving size that allowed it to round Parkay Spray’s fat and calorie content to zero. 21 C.F.R. § 101.62(b)(i).

Conagra markets Parkay Spray to “health conscious” consumers. Ex. 10, 6 [REDACTED]; Ex. 53 ([REDACTED]); see also Ex. 54 [REDACTED]. Ex. 55, CAGAL_007745 and CAGAL_007748. In addition to being the only Parkay tablespread labelled “0g fat/0 calories,” Parkay Spray is also [REDACTED].” *Id.*

2. Conagra Ignored Evidence That Parkay Spray’s Serving Size Was False While Suppressing Knowledge of Its True Fat and Calorie Content

During the period from 2008-2016—after Conagra added its “0g Fat/0 Calories” claims to Parkay Spray’s label—[REDACTED] Patek Decl., ¶¶ 38-43; Exs. 36 (summary) & 56-57 (original records). [REDACTED] Patek Decl., ¶ 41. [REDACTED], ¶ 43. One person noted [REDACTED].” Ex. 58. Another scolded Conagra for [REDACTED]” Ex. 36 (caseid 60412135).

Conagra [REDACTED]

Ex. 58. Internally, Conagra admitted that [REDACTED]
 [REDACTED]” Ex. 59. Conagra withheld the real fat content of Parkay Spray from consumers, [REDACTED]
 [REDACTED]” *Id.*, at 2.
 Conagra even [REDACTED]
 [REDACTED] t. Ex. 60 at 34:12-25, 35:23-36:3, 36:14-19; 37:8-14; 44:7-45:15, 46:9-14.

F. After this Lawsuit Was Filed, Conagra’s Lawyers Created Post-Hoc “Evidence” to Support Conagra’s Actions

In late 2018, Conagra’s counsel hired Sarah Butler, a professional expert witness, to perform a survey directed to Parkay Spray’s usage. Dkt. 253-24. Conagra did not provide Ms. Butler with its data showing Parkay Spray was used primarily as a topping. *Id.*; Ex. 61 at 30:18-24; Dkt. 253-25 at Ex. B. Nor did Ms. Butler consider survey procedures the FDA uses to create its RACCs. *Id.*; Ex. 61 at 30:5-10. Whereas the FDA collects usage data within 24 hours of food consumption, Ms. Butler asked people who believed they had purchased Parkay Spray within the last eight years to try to recall the exact number of sprays they had used up to eight years earlier. Dkt. 253-25, Ex. C, S10; cf. <https://data.nal.usda.gov/dataset/what-we-eat-america-wweia>-database (dietary intake component of FDA survey collects “two days of 24-hour dietary recall data” using in-person interview followed by phone interview). Butler also displayed Conagra’s suggested serving sizes of 1 spray for cooking and 5 sprays for topping to all recipients prior to asking them what serving size they use, unlike the FDA studies, which do not prime participants in this way. *Id.*, Ex. D. Even with these deep methodological flaws, the results still indicate that fewer than 3% of consumers use Parkay Spray’s labelled serving size of “1 spray,” and that the actual amount of Parkay Spray consumers use is an average of *seven* sprays when used as a topping, meaning more than 0.5 grams of fat, which would not permit rounding to zero. Dkt. 253-24 at 22; Patek Decl., ¶ 74.

Butler also purports to prove that Parkay Spray is primarily used as a cooking spray. To do so, Butler’s survey replaced the actual product name Parkay Spray with the phrase “Parkay *cooking spray*/topping”, a textbook example of improperly priming survey respondents to give a desired response. Ex 66. Butler displayed the phrase “Parkay *cooking spray*” to participants in

three consecutive questions, then asked them in the next question what the primary use of “Parkay *cooking spray*/topping” was. Not surprisingly, a majority responded “cooking spray,” though over 30% still responded “topping.” Ms. Butler, who never reviewed the NET survey, provided no explanation why her survey findings were diametrically opposed to those of NET, Conagra’s primary source of usage data. Neither Ms. Butler nor Conagra can explain why, if Parkay Spray’s primary use is as cooking spray, Conagra’s 30(b)(6) witnesses testified that was a trivial use, or why Conagra has not tested Parkay Spray as a cooking spray, advertised its use as a cooking spray, or performed a competitive analysis comparing it to any cooking sprays.

Conagra also purports to have FDA “approval” establishing that Parkay Spray is properly labeled with the RACC for “spray type” oils, in the form of a May 22, 2019 email from Jillone Kevala and (2) a September 6, 2019 letter from Douglas A. Balentine.³ See Dkt. 261 at p. 8; Ex. 11 at 148:17-149:6; Ex. 61 at 28:10-16. Under FDA regulations, the FDA correspondence is nothing more than the opinions of those employees, *not the agency*, because Conagra did not use the FDA’s formal petition procedure, did not provide the FDA with the NET data [REDACTED] [REDACTED]” and did not give the FDA notice of either the pending lawsuit or the arguments or evidence presented by Plaintiffs in this case. Ex. 65. Further, the Balentine letter was written by the former Director of Nutrition Sciences at Unilever, Ex. 11 at 148:17-149:6 & 66, which was also sued for claiming 0 grams fat on its I Can’t Believe It’s Not Butter! Spray based on the “Spray Types” RACC. *Pardini v. Unilever United States, Inc.*, No. 13-1675 SC, 2014 WL 265663, at *6 (N.D. Cal. Jan. 22, 2014). According to Dr. Balentine’s CV, his job responsibilities included substantiating Unilever’s labeling claims and supporting Unilever’s legal department. Ex. 66. Balentine’s letter does not acknowledge that conflict or experience.

III. ARGUMENT

Plaintiff is entitled to partial summary judgment on her claim that Conagra’s labeling of Parkay Spray is unlawful under the UCL because there is no genuine dispute of material fact that

³ Ms. Kevala and Mr. Balentine claim to work at the Center for Food Safety and Applied Nutrition, FDA’s Office of Nutrition and Food Labeling, as Supervisor Chemist and Director, respectively.

the labeling violates FDAs regulations.⁴ Under Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is proper if the record shows “that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party has the initial burden to show the absence of a genuine dispute of material fact as to the claims or parts thereof that she seeks to have summarily adjudicated. *Pyramid Tech., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 818 (9th Cir. 2014). The burden then shifts to the nonmoving party to present evidence showing a genuine issue for trial. *MetroPCS, Inc. v. City and Cnty of San Francisco*, 400 F.3d 715, 720 (9th Cir. 2005). Although the Court must view the evidence in a light most favorable to the nonmoving party, the nonmoving party must do more than present some evidence as to an issue it asserts is in dispute. *Id.* at 251. Further, “a court has the discretion to find **expert testimony** inadmissible— or decline to consider **expert testimony** on summary judgment — where it is unreliable or misleading.” *Volterra Semiconductor Corp. v. Primarion, Inc.*, 796 F. Supp. 2d 1025, 1045-46 (N.D. Cal. 2011).⁵

A. Conagra’s Label for Parkay Spray is Unlawful under the UCL.

The UCL is a broad statute providing remedies for a wide range of problematic business practices. *See Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1140 (9th Cir. 2012) (citing *Cel-Tech Comm’s, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 180 (1999) (“[T]he UCL’s ‘coverage is sweeping, embracing anything that can properly be called a business practice and that at the same time is forbidden by law.’”)). In particular, it prohibits “three varieties of unfair competition”: practices that are “unlawful,” “unfair,” or “fraudulent.” *Rubio v. Capital One Bank*, 613 F.3d 1195, 1203 (9th Cir. 2010) (citing *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1127 (9th Cir. 2009) and *S. Bay Chevrolet v. Gen. Motors Acceptance Corp.*, 72 Cal.App.4th 861, 85 Cal.Rptr.2d 301, 316 (1999)). In prohibiting “unlawful” business practices, the UCL “borrows

⁴ Although not required for this motion, there is also no genuine dispute on the sole other element of UCL liability: that Ms. Allen lost money or property as a result of her purchase. *See* Dkt. 93 (Decl. of Erin Allen that she would not have purchased absent the misrepresentation).

⁵ Partial summary judgment is available under Rule 56(a). *Harper v. City of San Jose*, No. C 09-05758 JW, 2011 WL 7109218, at *1 (N.D. Cal. Mar. 7, 2011); *Brown v. Hain Celestial Grp., Inc.*, No. 11-cv-03082-LB, 2015 U.S. Dist. LEXIS 67912, at *7 (N.D. Cal. May 26, 2015).

violations of other laws and treats them as unlawful practices that the unfair competition law makes independently actionable.” *Wilson*, 668 F.3d at 1140 (citing *Cel-Tech*, 20 Cal. 4th at 180). Thus, a “[v]iolation of almost any federal, state, or local law may serve as the basis for a UCL claim.” *Hadley v. Kellogg Sales Co.*, No. 16-CV-04955-LHK, 2019 U.S. Dist. LEXIS 136791, at *54 (N.D. Cal. Aug. 13, 2019). This includes violations of FDA regulations promulgated under the Food, Drug, & Cosmetic Act (“FDCA”). *See id* at *72 (“GRANT[ing] Plaintiff’s motion for partial summary judgment” that “Kellogg violated and is liable under the UCL’s ‘unlawful’ prong” because Kellogg’s label “violates 21 C.F.R. § 101.71(a) and thus violates the FDCA.”).

1. A Product is Misbranded Under the FDCA if its Serving Size Does Not Follow the FDA’s Standardized RACCs.

The FDCA states that a food is misbranded unless it bears a nutrition label providing a serving size in “an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food.” 21 U.S.C. § 343(q)(1)(A)(i). It requires the label to provide the fat and calorie content per serving. *Id.* at § (q)(1)(C). The corresponding regulations provide that the “customarily consumed” amount must be determined “based on consumption data under actual conditions of use.” 21 C.F.R. § 101.12(a)(3). To prevent food manufacturers from manipulating serving sizes to make their products appear more attractive, the FDA provides serving sizes for 131 food product categories in the form of a Reference Amount Customarily Consumed (“RACC”), which is based on national survey data regarding consumption patterns. 55 F.R. 29517; *see* 21 C.F.R. § 101.12, Table 2 (“Serving Size Table”). The RACC must be selected “based on *major intended use* (e.g., milk as a beverage and not as an addition to cereal).” 21 C.F.R. § 101.12(a)(7). Apart from a few exceptions not applicable here, a “serving size declared on a product label shall be determined from the [RACCs].” 21 C.F.R. § 101.9(b)(2).

The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased. 21 C.F.R. § 101.12(a)(8). Substitute products, such as a “low calorie” version, must use the same serving size “as the food for which it is offered as a substitute.” 21 C.F.R. § 101.12(d). This allows consumers to easily and readily make comparisons of nutrient content among products. 55 F.R. 29517. If a manufacturer believes there is no appropriate category

for its food product, the manufacturer ***must contact the FDA with evidence to support its serving size to have its serving size approved.*** 21 C.F.R. § 101.12(h). Alternatively, if no category fits the product's primary intended use, a manufacturer can petition the FDA for a new category. 21 C.F.R. § 101.12(h); 58 F.R. 2273. Manufacturers cannot deviate from the RACC for the product's primary intended use. However, for secondary uses that differ by two-fold or more from the reference amount, manufacturers may include a second column of nutritional information (including fat and calories) ***based on the amount customarily consumed*** in that use. 21 C.F.R. § 101.9(b)(11).

FDA regulations also require that food labels declare the amount of fat and calories per serving (based on appropriate serving sizes). *See* 21 C.F.R. § 101.9(c). In particular, a product may be labeled 0-fat only if it contains less than 0.5 g of fat per serving and 0-calories only if it contains less than 5 calories per serving. 21 C.F.R §§ 101.60(b)(i) & 101.62(b)(i). With dual serving sizes, rounded-down statements are allowed outside of the nutritional panel ***only if both serving sizes support the designation.*** 21 C.F.R. § 101.9(b)(12)(ii) (requiring a statement setting forth the basis upon which a nutrient content claim is made when a nutrient content claim is made on the label of a product that uses a dual column).

2. The Butter, Margarine, Oil, Shortening RACC category includes “All Spreads,” including Liquid Vegetable Oil Spreads.

The relevant portion of the Serving Size Table for Fats and Oils is as follows:

Fats and Oils:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (_g); 1 tbsp (15 mL)
Butter replacement, powder	2 g	_tsp(s) (_g)
Dressings for salads	30 g	_tbsp (_g); _tbsp (_mL)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	_tbsp (_g)
Spray types	0.25 g	About _seconds spray (_g)

Section 101.12 states explicitly that “butter” and “margarine” have an RACC of one tablespoon. Under § 101.12(d), “substitutes” for butter and margarine must use the same serving size so that consumers can compare the two products’ nutrient claims. 21 C.F.R. § 101.12(a)(9) and 101.12(d); 55 F.R. 29517; *see also* Nutrition Labelling and Education Act of 1990, Pub. Law

1 110-535, 104 Stat. 2353 (Nov. 8, 1990) (regulations shall require labels to “enable[] the public to
 2 readily observe and comprehend [nutritional] information and to understand its relative
 3 significance in the context of a total daily diet.”). FDA guidance reflects its intent that
 4 manufacturers use the same RACC for butter, margarine, and all table spreads when it states that
 5 the “butter, margarine, oil, shortening category encompasses “*[a]ll types of butter and margarine*
 6 *spreads* (regular, diet, lite/light, *liquid*, and whipped); oils; and shortenings.” Ex. 67. Further, the
 7 “form” of spreads includes “liquid margarine,” which is similar to margarine, both being emulsions
 8 of vegetable oil and water. 21 C.F.R. § 101.12(a)(8).

9 From 1992 until 2018, the FDA guidance stated that “spray type[]” fats and oils referred to
 10 in § 101.12 are “nonstick cooking sprays (e.g. Pam).” Ex. 67. In 2018, it edited that non-binding
 11 guidance to clarify that “spray types” include “[a]ll types of cooking sprays (e.g. cooking spray
 12 olive oil”).” Ex. 68. The FDA deleted the word “nonstick,” but “cooking sprays” are defined by
 13 their ability to prevent sticking, so that edit merely removed a redundancy. See evidence cited at
 14 section II.D.1.

15 **3. There is No Genuine Dispute That Parkay Spray is a “Spread” Primarily Used as** 16 **a Butter-Flavored Topping in Place of Butter and Margarine.**

17 As this Court stated when rejecting Conagra’s preemption defense, Plaintiff’s allegation is
 18 “not simply . . . that some consumers use Parkay Spray as a topping, but rather that ConAgra
 19 markets it to be used in that way by communicating to consumers that it is a butter substitute.” Dkt.
 20 231 at 17. As a butter/margarine substitute, Parkay Spray should be labeled in accordance with the
 21 food it imitates, which is butter and margarine, with a RACC of one tablespoon. Based on the
 22 evidence discussed in detail above, there is no genuine dispute Parkay Spray is anything other than
 23 a vegetable oil spread intended to be used primarily as a liquid butter-flavored topping.

24 First, Conagra admits that *it intends Parkay Spray to be used primarily as a topping in*
 25 *place of butter*. See section II.C, above. Specifically, Mr. Fitzgerald admitted that [REDACTED]
 26 [REDACTED] and is intended to be used [REDACTED]
 27 [REDACTED] Ex. 12 at 62:14-63:9 and 198:14-17. This admission is
 28 dispositive with respect to Parkay Spray’s major intended use. Conagra’s documents corroborate

1 that it marketed Parkay Spray as a spread/topping, and that Parkay Spray's dietary usage and
2 characteristics are like margarine. See section II.C.2, *supra*; 21 C.F.R. 101.12(a)(9).

3 Second, Conagra admitted that *consumers in fact use Parkay Spray primarily as a topping*
4 *in place of butter*. Specifically, its 30(b)(6) witness testified that the "[REDACTED]
5 [REDACTED]
6 [REDACTED]." Ex. 12
7 at 47:19-48:3. Its witnesses also affirmed that [REDACTED]
8 [REDACTED]. See section II.C.1, above. They acknowledged that Parkay
9 Spray's primary audience is [REDACTED]
10 [REDACTED]. And Conagra's business records—as well as all relevant industry studies and market reports—
11 corroborate its witnesses' testimony, consistently referring to Parkay Spray as a product that
12 competes with butter, margarine, and other tablespreads, and as one that is used almost exclusively
13 as a butter-flavored topping in place of butter and margarine. ⁶ See section II.C, above.

14 **B. Conagra's Argument That It Gets to Use the Cooking Spray RACC is Untenable**
15 **and Fails to Justify Its Arbitrary "5 Spray" Topping Serving Size.**

16 Parkay Spray's labels include *two* serving sizes. Exs. 1-3. Under the NLEA and FDA
17 regulations, *Conagra must have evidence that each serving size is proper* and supports the 0-fat
18 and 0-calorie claims on the front label. 21 C.F.R. § 101.9(b)(12)(ii). For Conagra to survive
19 summary judgment, the record must contain sufficient facts for a reasonable jury to find *both* that:

20 ⁶ Parkay Spray may be used as a "substitute" for butter and margarine under 21 C.F.R. § 101.13(d),
21 because it "may be used interchangeably with another food that it resembles, i.e., [] it is
22 organoleptically, physically, and functionally (including shelf life) similar to, and [] it is not
23 nutritionally inferior...." *Id.* Parkay Spray tastes, looks, smells, and feels like liquid butter and
24 margarine. It is physically similar to margarine, because it shares the same basic composition (i.e.,
25 an emulsion of vegetable oil and water), requires refrigeration, and has a similar shelf-life (about 6
26 months). Its [REDACTED] ingredients are nearly identical to that of Parkay Squeeze,
27 which Conagra also identifies as a liquid margarine "spread." Ex. 26; Ex. 11 at 71:1-74:7. Because
28 margarine (including its liquid form) is recognized as a substitute for butter, see, e.g., Ex. 47
[REDACTED], Parkay Spray's physical
similarity to margarine makes it a substitute for butter as well. Parkay Spray is not "nutritionally
inferior" because it contains added vitamin A, as required by law for all spreads used as margarine
substitutes. Ex. 1, Ex. 51; 21 C.F.R. § 160.110(a)(3). The fact that Conagra adds vitamin A to
Parkay Spray is yet another admission that the product is a margarine/butter substitute.

(1) Parkay Spray is primarily intended to be used as a cooking spray; **and** (2) Parkay Spray’s alternate serving size (5 sprays) is based on the amount customarily consumed in its promoted use as a topping. The record does not support either conclusion, let alone both.

1. Conagra Arbitrarily Chose the “5 Spray” Serving Size “For Topping.”

Even if Parkay Spray were primarily used as a cooking spray, Parkay Spray’s labelled serving size “for topping” would be still be illegal, since it is not based on a reference amount customarily consumed for that promoted use. *See* 21 U.S.C. § 343(q)(1)(A)(i) (serving size must be “an amount customarily consumed . . . that is appropriate to the food”); 21 C.F.R. § 101.9(b)(11) (the manufacturer “shall provide a second column of nutritional information *based upon the amount customarily consumed in the promoted use*”) (emphasis added); *see* 21 C.F.R. § 101.9(b)(12)(ii) (limiting nutrient content claims for dual column labeling unless a serving size is designated for that claim). Any secondary serving size must be based on evidence of customary usage. 21 C.F.R. § 101.9(b)(11). Conagra has none.

The “one gram” serving size “for topping” does not correspond to any reference amount in the Serving Size Table and is not, therefore, based upon the customary usage study of the FDA or other federal agency. *See* 21 C.F.R. § 101.12, Table 2, FN 1 (explaining that the reference categories are based upon National Consumption Surveys conducted by the U.S. Department of Agriculture). If Conagra did not agree with the “one tablespoon” serving size in the RACC, it was required to contact the FDA and seek approval of a new serving size or new reference category. 21 C.F.R. § 101.12(h); 58 F.R. 2273.

Conagra admits that it had [REDACTED]
[REDACTED]. *See* section II.E.1, above (citing testimony of Fitzgerald and Chatzidakis). [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] *See* section II.E2, above.

Conagra also testified that its “5 sprays” serving size was [REDACTED]. See section II.E.1, above. This is flawed, legally deficient reasoning. *See* Dkt. 41 at 11:2-3. Relying on Conagra’s arbitrary serving size definitions—which not coincidentally “happen” to be just low enough to support Conagra’s “0 g Fat/0 Calories” claims—would defeat the purpose of the regulations’ insistence on objective and uniform labeling. *Id.* Conagra knew that Parkay Spray was being used as a topping in place of butter and margarine, so it was legally required to use the one tablespoon RACC for that promoted use. And while Conagra protests that it simply continued a prior label, that is no defense to its unlawful act.

2. There Is No Triable Issue of Fact Regarding Whether Conagra Misclassified Parkay Spray as Primarily Intended “for Cooking.”

Conagra’s only justification for deviating from the FDA-mandated one tablespoon serving size for butter and margarine substitutes (other than its desire to claim 0 fat and 0 calories) is that it gets to claim the 0.25 gram RACC serving size for “Spray Types.” Not so.

All admissible evidence shows that Parkay Spray’s “major intended use” under 21 C.F.R. § 101.12(a)(7) is not as a cooking spray, so it is not correctly labeled as a “spray type” oil. At all times, the FDA has consistently indicated that the “spray type[]” fats and oils category is for “cooking sprays,” which are by definition intended to create a non-stick cooking surface.⁷ *See* evidence cited at section II.D.1. But in any event, Parkay Spray is not even marketed for *any* use in “cooking.”

First, by its own admission, Conagra does not *promote* Parkay Spray as a cooking spray. See section II.D.2, above. For instance, while Pam is explicitly labeled “No-stick **cooking spray**,” Parkay Spray’s front label does not mention “cooking.” *Compare* Ex. 1 *with* Ex. 43. Pam’s label shows a cooking pan; Parkay Spray’s depicts an image of liquid-topped corn. *Id.* While advertisements for Pam highlight its no-stick and easy clean-up properties, advertisements for Parkay Spray emphasize its “buttery taste” when placed on food. See, e.g., Exs. 1-3, 19-24.

⁷ In 2018, the FDA edited its non-binding guidance to clarify that “spray types” include “[a]ll types of cooking sprays (e.g. cooking spray olive oil).” The FDA’s 2018 non-binding guidance still limited “spray type” oils and fats to “**cooking** sprays” and in no way suggests that sprayable toppings with oil in them qualify for the “Spray Type” RACC.

Conagra's 30(b)(6) witnesses also [REDACTED]
 [REDACTED] See section II.CA.1 and II.D.2, above. They also testified [REDACTED]
 [REDACTED]. See section II.D, above. Further, the
 same Conagra documents that [REDACTED]
 [REDACTED]. See sections II.A.2 and II.D, above.
 All third party market reports relied on by Conagra do the same. See *id.* and section II.A.3, above.

Additionally, Conagra's testimony and documents show that Conagra did not design Parkay Spray to be a cooking spray. Conagra [REDACTED]
 [REDACTED] See section II.D.2 above. Conagra
 provides no recipes for use of Parkay Spray. It [REDACTED]
 [REDACTED] making it even less suitable to coat a cooking surface. It is over 50% water; once the
 water evaporates, the 0.09 grams of oil in one spray is far too little oil to be functional for cooking.
 Ex. 51 ¶¶ 34-44. And because Conagra added milkfat, Parkay Spray creates a dark gummy build
 up on pans at sautéing temperatures—an undesirable quality for cooking sprays. *Id.*

3. Conagra's After-the-Fact Survey Does Not Create a Genuine Dispute.

In the absence of any evidence to support its "5 spray" serving size, Conagra tries to
 manufacture some with a post-litigation survey from Sarah Butler. Should Conagra choose to
 submit the Butler Survey, Plaintiff will object under *Daubert*. See generally L.R. 7-3. Butler biased
 responses by showing the labelled serving size *before* asking how much respondents consumed,
 and by replacing the product's real name with the phrase "*Parkay cooking spray/topping*." Ex. 65;
 Ex. 66. Butler's survey does not comply with the FDA requirement that survey data be based on
 "consumption data *under actual conditions of use*," (such as a contemporaneous diary or 24-hour
 recall interview), but instead asks respondents to recall how many sprays they used up to *eight*
years ago, which is scientifically unsound. These and other flaws render her opinion inadmissible.
 See e.g., *United States v. Williams*, No. 13-CR-00764-WHO, 2016 WL 899145 (N.D. Cal. Mar. 9,
 2016) (expert testimony excluded due to failure to apply reliable scientific methods); *Kournikova*
v. Gen. Media Communs., Inc., 278 F. Supp. 2d 1111, 1125 (C.D. Cal. 2003) (survey excluded for
 failure to sample appropriate population).

1 Additionally, “expert declarations do not automatically create genuine issues of fact. . . .
 2 [W]hen the ***indisputable record contradicts or otherwise renders the opinions unreasonable***, they
 3 cannot be relied upon.” *W. Parcel Express v. UPS of Am.*, 65 F. Supp. 2d 1052, 1060 (N.D. Cal.
 4 1998) (emphasis added). That is the case here. Butler ignores that all of Conagra’s testimony and
 5 business records directly refute her. *See Volterra*, 796 F. Supp. 2d at 1044 (“[I]f ‘the trial court
 6 concludes that the scintilla of expert evidence presented supporting a position is insufficient to
 7 allow a reasonable juror to conclude that the position more likely than not is true, the court remains
 8 free to grant summary judgment.’”) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579,
 9 596 (1993)) (alterations omitted).

10 Regardless, the Butler Survey does not create a fact issue because it ***still shows that***
 11 ***Conagra’s labeling was unlawful***. Even according to her data, fewer than 3% of consumers use
 12 the labelled serving size of 1 spray, and the average serving size for Parkay Spray as a topping is at
 13 ***least 7 sprays***. Patek Decl., ¶74. Had Conagra used the seven-spray serving size, which Plaintiff
 14 still contends underrepresents true usage, Conagra could not have rounded the fat content down to
 15 zero. The actual fat content would have been approximately .77 grams, which is above the
 16 threshold for rounded-down statements. 21 C.F.R. § 101.62(b)(i).

17 **4. Conagra’s FDA Correspondence Is Not Evidence of Anything.**

18 In deposition, Ms. Butler cited correspondence between individuals at the FDA and
 19 Conagra’s counsel as evidence that the “Spray Types” category encompasses “fats and oils
 20 dispensed via a manual pump.” Ex. 61 at 28:10-16. This FDA correspondence is not entitled to any
 21 deference from this Court, nor is it persuasive.

22 The Supreme Court has held that certain agency determinations are entitled to deference,
 23 the highest form of which is called “*Chevron* deference.” It applies to official agency actions such
 24 as rulemaking and adjudicating that “have the force and effect of federal law.” *Reid v. Johnson &*
 25 *Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (citing *Chevron U.S.A. Inc. v. Natural Res. Def.*
 26 *Council, Inc.*, 467 U.S. 837, 843-44 (1984)). Such actions “are given controlling weight unless
 27 they are arbitrary, capricious, or manifestly contrary to the statute.” *Chevron*, 467 U.S. at 843.

28 A much lesser form of deference is given to an ***agency’s official*** interpretations of its own

1 regulations, “such as those in opinion letters . . . policy statements, agency manuals, and
 2 enforcement guidelines.” *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). These “are
 3 entitled to respect . . . but only to the extent that those interpretations have the ‘power to
 4 persuade.’” *Id.* Even an agency’s official interpretation is entitled to no deference when it is
 5 “plainly erroneous or inconsistent with the regulation, or when there is reason to suspect that the
 6 interpretation does not reflect the agency’s fair and considered judgment on the matter.”
 7 *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 143-44 (2012) (internal citations
 8 omitted). “[U]nofficial interpretations which the agency itself does not view as binding,” receive
 9 no deference. *Echevarria v. Chi. Title & Tr. Co.*, 256 F.3d 623, 629 (7th Cir. 2001).

10 The FDA specifies how to obtain an “advisory opinion” that “represents the formal position
 11 of the FDA on a matter.” The party must submit a request that includes a “full statement of all facts
 12 and legal points relevant to the request” and a certification that “to the best of [the requester’s]
 13 knowledge and belief, this request includes all data, information, and views relevant to the matter,
 14 whether favorable or unfavorable to the position of the undersigned, which is the subject of the
 15 request.” 21 C.F.R. § 10.85(b). A “statement made or advice provided by an FDA employee
 16 constitutes an advisory opinion **only** if it is issued in writing under this section.” *Id.* § 10.85(k)
 17 (emphasis added). Where FDA employees provide statements that **do not comply with § 10.85**, any
 18 such opinion “is an informal communication that represents the best judgment of that **employee** at
 19 that time but does not constitute an advisory opinion, . . . and **does not bind** or otherwise obligate
 20 or commit the agency to the views expressed.” *Id.* (emphasis added).

21 It is beyond dispute that the communication at issue here is *not* an official agency opinion,
 22 because Conagra did not comply with 21 C.F.R. § 10.85’s requirements. Conagra did not include
 23 “all data, information, and views relevant to the matter, whether favorable or unfavorable to the
 24 position of the undersigned,” nor the required certification. 21 C.F.R. 10.85; Ex. 63.⁸ Thus, the

25
 26 ⁸ For example, Conagra’s request does not disclose (i) this litigation, (ii) the contrary NET survey
 27 data, (iii) Conagra’s contradictory testimony and records, (iv) the hundreds of complaints and
 28 inquiries Conagra has received about its label, (v) the Butler survey’s finding that only 3% of
 consumers use the labelled “1 spray” serving size, and that the average serving is 7 sprays “for
 topping”, or (vi) that, at cooking temperatures, over half of each spray of Parkay Spray will have
 evaporated, so 2-3 sprays must be used to provide 0.25 g of oil. *See* Ex. 63.

1 statements in these communications are nothing more than the non-binding opinions of those
 2 *individual employees*. It is not entitled to any deference nor is it evidence of anything.

3 Even if the Court were to consider the FDA correspondence as the official position of the
 4 FDA, it is still not entitled to deference. First, as this Court has previously noted, “Judge Tigar
 5 found—and I agree—that the regulations are unambiguous. See [Dkt 41,] 12. As a result, I have
 6 no need to rely on the agency’s interpretation, and it does not control as it might in the face of an
 7 ambiguous regulation.” Dkt 231, 17. Second, because Conagra did not provide the FDA with all of
 8 the relevant facts, the correspondence cannot reflect the agency’s “fair and considered judgment on
 9 the matter.” *Christopher*, 567 U.S. at 143-44. Third, the correspondence is analytically deficient. It
 10 lacks any discussion of § 101.12; any reference to the definition of “cooking spray;” and any
 11 explanation of the inconsistency in referring to a manual-pump spray using a duration-based
 12 “About __ seconds spray” serving size. Nor did it address the FDA’s criteria for grouping foods
 13 within a given RACC set forth in § 101.12, including (i) appropriate national survey data
 14 supporting the claimed serving size for Parkay Spray (which is nonexistent), (ii) whether “for
 15 cooking” represented the “major intended use” of Parkay Spray and similar liquid spreads (which it
 16 does not), and (iii) whether Parkay Spray and cooking sprays such as Pam have “similar dietary
 17 usage, product characteristics, and customarily consumed amounts” (which they do not). In short,
 18 the proffered interpretations of “spray types” are arbitrary and baseless, inconsistent with the plain
 19 language and rationale of prior FDA guidance, and lack persuasive argument from documented
 20 facts to a reasoned position. The Court should ignore them. *See Mead*, 533 U.S. at 228.

21 **IV. CONCLUSION**

22 For the foregoing reasons, Plaintiff respectfully requests that this Court grant her motion
 23 for partial summary judgment.

24 Dated: June 17, 2020

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